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# Regulatory Decision Summary - COMIRNATY - Health Canada

## Regulatory Decision Summary for COMIRNATY

### Medicinal ingredient(s):

tozinameran

### Therapeutic area:

Vaccines, for human use

### Type of submission:

New Drug Submission [COVID]

### Control number:

252736

#### ▼ What was the purpose of this submission?

The purpose of this submission is to transition the regulatory status of the Pfizer-BioNTech Covid 19 vaccine from being authorized under the Interim Order (IO), to being authorized under Division 8 of the *Food and Drugs Regulations*. The brand name of the vaccine is now COMIRNATY.

COMIRNATY (previously known as Pfizer-BioNTech COVID-19 Vaccine) is now authorized for use in relation to the COVID-19 pandemic, in accordance with the *Food and Drug Regulations*.

COMIRNATY is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) in individuals 12 years of age and older.

There is no change to the recommended Directions for Use.

For more information, refer to the Product Monograph for COMIRNATY.

Terms and conditions were imposed upon the authorization, with respect to Clinical, Chemistry and Manufacturing, Labelling, and Risk and Management Plan requirements.

#### ▼ Why was the decision issued?

The information below summarizes the rationale for approval of the vaccine under the *Food and Drug Regulations*. Some of this information is already available in previous Summaries of Rationale for Approval that were published when this vaccine was authorized under the Interim Order.

COVID-19 is a serious and potentially fatal or life-threatening human infection. Vaccination is an important way to protect against the disease and help stop the pandemic.

The safety and efficacy of COMIRNATY were evaluated in a multicenter, multinational, randomized, placebo-controlled, observer-blind study. A total of 44,047 participants (22,026

received vaccine and 22,021 received placebo) in the Phase 3 study were 16 years of age or older and 2,260 participants were 12 to 15 years of age (1,131 in the vaccine group and 1,129 in the placebo group). A total of 8,018 participants were 65 years of age and older (3,980 in the vaccine group and 4,038 in the placebo group).

In the primary analysis (data cut-off date November 14, 2020), the vaccine efficacy against COVID-19 was 95.0% (95% confidence interval [CI]: 90.3% to 97.6%) in participants 16 years of age and older without evidence of prior infection with SARS-CoV-2 at 7 days after Dose 2, which met the efficacy pre-specified success criterion. In a subgroup analysis of adolescent 12 to 15 years of age, the vaccine efficacy was 100% (95% CI: 75.3% to 100.0%).

An updated analysis (data cut-off dated March 13, 2021) showed a vaccine efficacy of 91.3% (95% CI: 89.0% to 93.2%) in participants 16 years of age and older without evidence of prior infection with SARS-CoV-2 at 7 days after Dose 2, based on COVID-19 cases accrued 6 months in a blinded placebo-controlled follow-up. The vaccine efficacy was 94.5% (CI: 88.3% to 97.8%) in participants 65 years of age and older.

The vaccine efficacy against severe COVID-19 was 95.3% (95% CI: 71.0% to 99.9%) in participants 16 years of age and older, with 1 and 21 cases in the vaccine and placebo groups, respectively. No severe COVID-19 cases were reported in adolescents (12 to 15 years of age) in the clinical study.

For the safety evaluation, after the second dose a total of 25,651 (58.2%) participants (13,031 in the vaccine group and 12,620 in the placebo group) 16 years of age and older were followed for up to 4 months; 3,082 (7.0%) participants (1,778 in the vaccine group and 1,304 in the placebo group) were followed up for 6 months and a total of 1,308 adolescents (660 in the vaccine group and 648 in the placebo group) were followed for 2 months during the blinded placebo-controlled follow-up period (data cut-off date March 13, 2021). The most common adverse reactions in participants 16 years of age and older after any dose included injection site pain (84.3%), fatigue (64.7%), headache (57.1%), muscle pain (40.2%), chills (34.7%), joint pain (25.0%), fever (15.2%), injection site swelling (11.1%), and injection site redness (9.9%).

Adverse reactions in adolescents 12 to 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%), based on the assessment of 1,308 adolescents 12 to 15 years of age who have been followed for at least 2 months after the second dose during the blinded placebo-controlled follow-up period.

Both solicited local and systemic adverse reactions were more commonly reported by participants in the vaccine group than in the placebo group, and the adverse reactions generally increased after Dose 2. Adverse reactions were usually mild or

moderate in intensity and resolved within a few days after vaccination.

For the unsolicited adverse events reported during the blinded placebo-controlled follow-up period in participants 16 years of age and older, lymphadenopathy was reported in 0.4% of participants (87 in the vaccine group and 8 the placebo group) which is plausibly related to vaccination; Bell's palsy (facial paralysis) was reported by four participants in the vaccine group and two in the placebo group. Serious adverse events were reported by 165 (1.8%) COMIRNATY recipients and 151 (1.7%) placebo recipients who received at least 1 dose of vaccine or placebo, respectively. Pericarditis was reported for one participant in the vaccine group, and no case was reported in the placebo group.

There were no notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events reported during the blinded placebo-controlled follow-up period of the study in adolescents 12 to 15 years of age, with the safety profile in these adolescents being comparable to that found in young adults 16 to 25 years of age. The data set was based on a total of 1,308 adolescents followed up for at least 2 months after Dose 2 during the blinded placebo-controlled period of the study. No deaths related to the vaccine were reported in the study. No cases of thrombotic events, myocarditis, erythema multiform, kidney inflammation or anaphylactic reaction following administration of the vaccine were reported in clinical trials.

Very rare cases of anaphylactic reactions and/or hypersensitivity reactions, myocarditis and/or pericarditis, or facial paralysis/Bell's palsy following administration of the vaccine have been reported outside of the clinical trials with Cominarty. An important limitation of the data is the lack of information on the long-term safety and effectiveness of the vaccine. The identified limitations are managed through labelling and the Risk Management Plan RMP).

The RMP is designed to describe known and potential safety issues, to present the monitoring plan and when needed, to describe measures that will be put in place to minimize risks associated with the product. Upon review, the RMP was considered to be acceptable and identified appropriate monitoring (pharmacovigilance) activities and risk minimization measures based on the safety profile of the product. This included providing information in the product monograph and identifying populations where more data are needed. The RMP will be updated to reflect additional safety information as this is collected. In addition to regulatory requirements for post-market monitoring and prioritized reporting of adverse events following immunization, monthly safety summary reports on the vaccine will be provided to Health Canada. Results related to safety and effectiveness from ongoing and planned studies will be submitted as they become available.

In conclusion, based on the data provided, the risk-benefit profile of COMIRNATY is considered favourable. The efficacy of

the vaccine was established and the vaccine was well tolerated by participants.

COMIRNATY is therefore recommended for authorization under *Food and Drug Regulations* for drugs for use in relation to COVID-19 and is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) in individuals 12 years of age and older.

▼ Decision issued

Approved; issued a Notice of Compliance in accordance with the Food and Drug Regulations

**Date of decision:**

2021-09-16

**Manufacturer:**

BioNTech Manufacturing GmbH. Importer: Pfizer Canada ULC.

**Drug Identification Numbers issued:**

02509210, 30 mcg/0.3 mL (6 doses of 0.3 mL per vial), suspension, Intramuscular

**Prescription status:**

COMIRNATY is a Schedule D drug.

**Date filed:**

2021-06-10

**Contact:**

Office of Regulatory Affairs - Biologic and Radiopharmaceutical  
Drugs Directorate (ORA-BRDD).

**Date modified:**

2020-11-13